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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,813	07/05/2005	John David Fraser	55502-007US1	2831

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OCCHIUTI ROHLICEK & TSAO, LLP  
10 FAWCETT STREET  
CAMBRIDGE, MA 02138

EXAMINER
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JUEDES, AMY E

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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08/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,813	<b>Applicant(s)</b> FRASER, JOHN DAVID	
	<b>Examiner</b> AMY E. JUEDES	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8,9,14,15,17 and 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,10-13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1644

### DETAILED ACTION

1. Applicant's amendment and remarks, filed 4/14/08, are acknowledged.

Claims 1, 3-14, 17-20, and 23 have been amended.

Claims 2 and 16 have been cancelled.

Claim 29 has been added.

Claims 1, 3-15, and 17-29 are pending.

2. Claims 5-6, 8-9, 14-15, 17, and 21-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1, 3-4, 7, 10-13, and 18-20 are being acted upon.

3. The objection to the declaration is withdrawn in view of Applicants submission of a new declaration on 6/6/08.

4. The rejections of the claims under 35 U.S.C. 112 first and second paragraph are withdrawn in view of Applicant's amendment to the claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 7, 10-13, and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45739 (of record), in view of Parks et al., 2002.

As set forth previously, WO 02/45739 teaches an immunomodulator comprising a SMEZ-2 superantigen with a defective TCR binding site coupled to an antigen (see pages 3 and 15 in particular). WO 02/45739 also teaches that residue D42 of SMEZ-2 is a critical residue for TCR binding that can be subjected to mutagenesis (see page 15 in particular). WO 02/45739 also teaches that it is useful to mutate TCR binding residues to cysteine in order to introduce a residue amenable to antigen coupling (see pages 18-19 in particular). WO 02/45739 also teaches coupling the antigen in a reversible manner, and a pharmaceutical composition or vaccine comprising the immunomodulator (see pages 3-4, in particular),

WO 02/45739 does not teach the SMEZ-2 coupled to ovalbumin.

Art Unit: 1644

Parks et al. teach that ovalbumin is a well characterized model antigen comprising defined epitopes that is useful for studying the immune response to vaccination (see page 1167 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make the SMEZ-2 antigen conjugate taught by WO 02/45739, using ovalbumin as the antigen, as taught by Parks et al. The ordinary artisan at the time the invention was made would have been motivated to do so, and have a reasonable expectation of success, since Parks et al. teach that ovalbumin is a well characterized model antigen comprising defined epitopes that is useful for studying the immune response to vaccination.

Applicant's arguments filed 4/14/08 have been fully considered, but they are not persuasive.

Applicant argues that 35 U.S.C. 103(c) disqualifies a 102(e) reference if the subject matter disclosed therein and the claimed invention were owned by the same person at the time the invention was made. Applicant states that the subject matter disclosed in WO 02/45739 and the present application were commonly owned by Auckland Uniservices Limited, as indicated by the cover pages for WO 02/45739 and WO 03/101173, upon which the present application is based.

However, the fact that the reference and the application have the same assignee is not, by itself, sufficient evidence to disqualify the prior art under 35 U.S.C. 103(c). There must be a statement that the common ownership was "at the time the invention was made." (see MPEP 706.02). The statement concerning common ownership should be clear and conspicuous. Although Applicant has stated that 103(c) disqualifies a reference if the subject matter disclosed therein and the claimed invention were owned by the same person at the time the invention, Applicant has not actually provided a clear statement that WO 0245739 and the present application were commonly owned at the time the invention was made.

Applicant further argues that WO 02/45739 does not qualify as prior art under 102(e) since the reference discloses the inventor's own work.

When a prior U.S. patent, U.S. patent application publication, or international application publication is not a statutory bar, a rejection based on a reference relied upon under 35 U.S.C. 102(e) can be overcome by antedating the filing date of the reference by submitting an affidavit or declaration under 37 CFR 1.131 or by submitting an affidavit or declaration

Art Unit: 1644

under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work. The mere statement of Applicant's attorney is not sufficient.

6. The following are new grounds of rejection necessitated by Applicant's amendment.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 7, and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of a construct wherein "in use" the construct can bind to Class II molecules. While the recitation of a construct that can bind to Class II MHC molecules is clear, the recitation of "in use" renders the claims indefinite. A construct is either capable of binding to Class II MHC molecules or not, and it is not clear what types of "uses" are required.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1644

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner  
Technology Center 1600

/G.R. Ewoldt/  
Primary Examiner, Art Unit 1644